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Registration Decision RD2014-16

Beauveria bassiana strain ANT-03

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Registration Decision for *Beauveria bassiana* strain ANT-03

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Beauveria bassiana* strain ANT-03 and the end-use products Bio-Ceres G WP and Bio-Ceres G WB, containing the technical grade active ingredient *Beauveria bassiana* strain ANT-03, to reduce numbers of whiteflies, thrips and aphids on greenhouse grown tomatoes, cucumbers and ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-06, *Beauveria bassiana* strain ANT-03. This Registration Decision[2] describes this stage of the PMRA's regulatory process for PRD2014-06 and summarizes the Agency's decision and reasons for it. The PMRA received no comments on PRD2014-06. This decision is consistent with the proposed registration decision stated in PRD2014-06.

For more details on the information presented in this Registration Decision, please refer to the PRD2014-06 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Beauveria bassiana* strain ANT-03?

Beauveria bassiana strain ANT 03 is a microbial pest control agent in the end-use products, Bio-Ceres G WP and Bio-Ceres G WB. These end-use products reduce numbers of whiteflies, aphids, and thrips on greenhouse tomato, cucumber and ornamentals.

Beauveria bassiana is a fungus that grows naturally in soils throughout the world. It is a generalist entomopathogenic fungus that causes a disease in many types of insect that is often fatal. While insects living in or near the soil have evolved natural defences against this fungus as it is common in their natural environment, it can be used as an insecticide against most other insects. The ANT 03 strain of *B. bassiana* was isolated in 2001 from a tarnished plant bug found dead in L'Île Perrot, Quebec.

Health Considerations

Can Approved Uses of *Beauveria bassiana* strain ANT-03 Affect Human Health?

***Beauveria bassiana* strain ANT-03 is unlikely to affect your health when Bioceres G WP and Bioceres G WB are used according to the label directions.**

People could be exposed to *Beauveria bassiana* strain ANT-03 when handling and applying Bioceres G WP and Bioceres G WB. When assessing health risks, several key factors are considered:

- The microorganism's biological properties (for example, production of toxic byproducts), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies, and the level that people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

- Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When the technical grade active ingredient, *Beauveria bassiana* strain ANT-03, was tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure that the food Canadians eat is safe.

Beauveria bassiana is encountered in nature as it is a ubiquitous soil microorganism that causes disease in insects. When the technical grade active ingredient was administered orally to rats, no signs of toxicity or disease were observed, and no metabolites of toxicological significance have been shown to be produced by this strain of *B. bassiana*. Therefore, the establishment of a MRL is not required for *B. bassiana* strain ANT-03. As well, the likelihood of residues contaminating drinking water supplies is negligible to nonexistent. Consequently, dietary risks are minimal to nonexistent.

Occupational Risks from Handling Bioceres G WP and Bioceres G WB

Occupational risks are not of concern when Bioceres G WP and Bioceres G WB are used according to label directions, which include protective measures.

Workers handling Bioceres G WP and Bioceres G WB can come into direct contact with *B. bassiana* strain ANT-03 on the skin or by inhalation. For this reason, the product label will specify that workers exposed to the end-use product must wear waterproof gloves, long-sleeved shirts, long pants, eye goggles, a dust/mist filtering respirator/mask (National Institute for Occupational Safety and Health [NIOSH] approval number prefix TC-21) or NIOSH-approved respirators (with any N-95, P-95, R-95 or HE filter), and shoes plus socks.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Bioceres G WP and Bioceres G WB Are Introduced Into the Environment?

Environmental risks are not of concern.

Bioceres G WP and Bioceres G WB contain *Beauveria bassiana* strain ANT-03, a fungus that infects insects. *Beauveria bassiana* occurs naturally in soils. The microorganism's ability to infect insects is achieved through the germination of a fungal spore on the insect cuticle, which then grows throughout the body and kills the insect.

Minimal environmental exposure to *B. bassiana* strain ANT-03 is expected following the proposed greenhouse use of Bioceres G WP and Bioceres G WB because the applications are made indoors.

Studies were conducted to determine the effects of the technical grade active ingredient, *Beauveria bassiana* strain ANT-03, on birds, and terrestrial and aquatic arthropods. These studies showed that the technical grade active ingredient was not pathogenic to birds; however, it may be pathogenic/toxic to insects and daphnids. As a result, the end-use product labels will contain statements identifying the potential for harm to beneficial insects and bees and that applications avoid direct contact to foraging bees. The end-use product labels will also contain standard statements restricting users from activities that may release *B. bassiana* strain ANT-03 into aquatic environments from its use in the greenhouse.

Although no other studies were considered, exposure to outdoor environments is expected to be minimal since the use is restricted to greenhouses, therefore, significant adverse effects to non-target organisms is not expected.

Value Considerations

What Is the Value of Bio-Ceres G WP and Bio-Ceres G WB?

Bio-Ceres G WP and Bio-Ceres G WB can be used to reduce numbers of whiteflies, aphids, and thrips on greenhouse tomato, cucumber and ornamentals.

Bio-Ceres G WP and Bio-Ceres G WB may be used on greenhouse tomato, cucumber and ornamentals as part of an integrated pest management program. The data reviewed demonstrated that Bio-Ceres G WP and Bio-Ceres G WB reduce numbers of whiteflies, aphids, and thrips on greenhouse tomato, cucumber and ornamentals. However, depending on humidity and temperature, efficacy can be variable. Multiple applications may be required for optimum performance of the products. This is not unexpected given the mode of action of these products (a fungus that causes a disease).

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Bioceres G WP and Bioceres G WB to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed to large quantities of Bioceres G WP or Bioceres G WB, respiratory and dermal sensitivity could possibly develop upon repeated exposure to the product since all microorganisms, including *B. bassiana* strain ANT-03, contain substances that are potential sensitizers. Therefore, anyone handling or applying Bioceres G WP or Bioceres G WB must wear appropriate waterproof gloves, a long-sleeved shirt, long pants, eye goggles, a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH-approved respirators (with any N-95, P-95, R-95 or HE filter), and shoes plus socks. Also, the signal words, "POTENTIAL SENSITIZER" are required on the principal display panel of the technical grade active ingredient, Bioceres G WP and Bioceres G WB; and the precautionary statements: "Avoid contact with eyes, skin and clothing," "Avoid inhaling/breathing mists" and "May cause sensitization" are required on the secondary display panel of the label for Bioceres G WP and Bioceres G WB.

Environment

The end-use product label will include environmental precaution statements that prevent the contamination of aquatic systems from the use of Bioceres G WP and Bioceres G WB, as well as statements identifying the potential for harm to beneficial insects and bees.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-06) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.